



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,035	06/23/2003	Mizuo Miyazaki	CPR-00101.P.1-US	9541
24232	7590	08/14/2006	EXAMINER	
DAVID R PRESTON & ASSOCIATES APC 5850 OBERLIN DRIVE SUITE 300 SAN DIEGO, CA 92121			AUDET, MAURY A	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,035	MIYAZAKI, MIZUO	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04/23/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-32, as drawn to method of using the elected invention compound Suc-Val-Pro-Phe^P(Oph)₂ in the reply filed on 05/26/2006 is acknowledged. The Examiner is willing to rejoin Group II, the composition as drawn to the elected invention compound Suc-Val-Pro-Phe^P(Oph)₂, as to both Group I and Group II. Claims 1-34 are examined on the merits. Claims 1-34 have been examined only in so far as they read on the above elected invention and rejoined composition/compound thereto. However, Applicant is requested amend the claims in scope to the above elected/rejoined group consisting of the active agent Suc-Val-Pro-Phe^P(Oph)₂.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Powers et al. (US 5,543,396; also cited in IDS of 04/23/04, P5).

Powers et al. teach a pharmaceutical composition in any form (inherently containing a diluent or excipient since can be in the form of e.g. tablet, aqueous or oily suspension, etc.) (col. 16, lines 23-40), comprising the elected compound of the invention Suc-Val-Pro-Phe^P(Oph)₂ (e.g. Example 17), describes at the “best inhibitor for [serine proteases] chymotrypsin and

Art Unit: 1654

chymotrysin-like enzymes” (col. 5, lines 40-44; col. 3, lines 50-53), which are involved in “tissue remodeling” [e.g. tissue adhesion formation] (col. 1, lines 41-43).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powers et al. (US 5,543,396; also cited in IDS of 04/23/04, P5) in view of Scharpe et al. (US 2002/0061839 A1).

Powers et al. is discussed above. Powers et al. teach a pharmaceutical composition in any form (inherently containing a diluent or excipient since can be in the form of e.g. tablet, aqueous or oily suspension, etc.) (col. 16, lines 23-40), comprising the elected compound of the invention Suc-Val-Pro-Phe^P(Oph)₂ (e.g. Example 17), describes at the “best inhibitor for [serine proteases] chymotrypsin and chymotrysin-like enzymes” (col. 5, lines 40-44; col. 3, lines 50-53), which are involved in “tissue remodeling” [e.g. tissue adhesion formation] (col. 1, lines 41-43). However, Powers et al. does not expressly teach the use of Suc-Val-Pro-Phe^P(Oph)₂ to reduce [tissue] adhesion formation (e.g. claim 1) or all the various forms of administration (e.g. claim 25-30, such as liposomes).

Scharpe et al. teach the use of serine protease inhibitors such as Suc-Val-Pro-Phe (para 69) in virtually any pharmaceutical admixture/formulation, such as liposomes (para 125).

Art Unit: 1654

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the elected compound Suc-Val-Pro-Phe^P(Oph)₂ to reduce [tissue] adhesion formation as one of the methods relevant to inhibiting the actions of the serine protease chymotrypsin methods in Powers et al., because Powers et al. advantageously teaches the use of Suc-Val-Pro-Phe^P(Oph)₂ to inhibit chymotrypsin, which is a serine protease known to be used in the pathway of tissue remodeling (e.g. adhesion/aggregation/binding), and one of skill in the art would recognize that administering Suc-Val-Pro-Phe^P(Oph)₂, even if not expressly stated, is administered in part or total to combat such tissue adhesion caused by chymotrypsin.

It would have been obvious to one of ordinary skill in the art at the time of the invention to put the elected compound Suc-Val-Pro-Phe^P(Oph)₂ in any formulation/admixtures (e.g. liposomes) in the composition of Powers et al, because Scharpe et al. teach that like exact or like serine protease inhibitors may be put in composition with e.g. liposomes, etc. depending on the desired result/administration route; just as Powers et al. likewise discussed in terms of motivation for route/type of administration being left open to the skilled artisan and the desired effect.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No.

10/544,254 (Miyazaki et al., Publication US 2006/0122101 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because even though the ‘254 expressly claims its subject matter in the form of a “medicament” only, therein, the limitations are directed to the presently elected compound Suc-Val-Pro-Phe^p(Oph)₂ in any formulation/admixtures, for the purpose of inhibiting tissue adhesion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 112 1st Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing adhesion formation (as well as postoperatively) between tissue surfaces (see e.g. Fig.'s 4-6, specification) using the protease inhibitor Suc-Val-Pro-Phe^P(Oph)₂, for a period of time sufficient to reduce adhesion formation; does not reasonably provide enablement for *preventing* adhesion formation between tissue surfaces using the protease inhibitor Suc-Val-Pro-Phe^P(Oph)₂. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated/disclosed that the claimed sequences may be used for reducing adhesion formation between tissue surfaces (see e.g. Fig.'s 4-6, specification) using the protease inhibitor Suc-Val-Pro-Phe^P(Oph)₂, for a period of time sufficient to reduce adhesion formation; and/or reducing the risk thereof. However, the claims also encompass using the claimed composition to prevent adhesion formation between tissue surfaces using the protease inhibitor Suc-Val-Pro-Phe^P(Oph)₂, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the term "treat", especially since it is notoriously well accepted in the medical art that the vast

Art Unit: 1654

majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing such disorders as ordinary tissue adhesion (which clearly is not recognized in the medical art as being a totally preventable phenomenon/condition).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed composition which would function to prevent prevent adhesion formation between tissue surfaces using the protease inhibitor Suc-Val-Pro-Phe^P(Oph)₂.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is to the composition, but depends back to method claims, which renders the claims unclear and improper. Applicant is requested to positively recite the elected/rejoined compound of the invention, namely consisting of Suc-Val-Pro-Phe^P(Oph)₂.

Claim Objections

Claim 34 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot itself depend from a multiple dependent claim (claim 33). See MPEP § 608.01(n).

Claim Observations

In claims 25, 27, 29, and 30, the term "claim" has been misspelled "claims".

Claims 25-30 depend from claim 1 directly or indirectly, the first independent claim grouping, but are sandwiched in the middle of the second independent claim grouping (claim 16). It is suggested, for clarity (and along with any other amendments) that Applicant consider amending the claims to delete claims 1-34 and start with new claims beginning at claim 25, wherein the claims are properly grouped.

Conclusion

No claims are allowed.

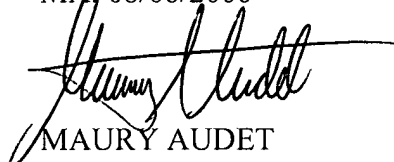
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA 08/06/2006

A handwritten signature in black ink, appearing to read 'Maury Audet', is written over the printed name.

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654